



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov



January 10, 2012

Senator John A. Alario, Jr., President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804

Re: **Report No. 1 of 3 for Regulatory Project 2011-1 ~ Pharmacist-in-Charge (PIC) Requirements**
Report No. 1 of 3 for Regulatory Project 2011-2 ~ Cognitive Services
Report No. 1 of 3 for Regulatory Project 2011-7 ~ Penal Pharmacy
Report No. 1 of 3 for Regulatory Project 2012-1 ~ E-Communications
Report No. 1 of 3 for Regulatory Project 2012-2 ~ Hospital Pharmacy
Report No. 1 of 3 for Regulatory Project 2012-3 ~ Remote Processing of Medical Orders

Dear Senator Alario:

The Board has initiated the rulemaking process to amend six different sections of its rules. For each of the six projects identified above, you should find the following documents in this packet:

- Insertion Order for the Louisiana Register
- Notice of Intent
- Proposed Rule
- Fiscal & Economic Impact Statement
- Regulatory Flexibility Analysis
- Family Impact Statement

As indicated in the notice, we will convene a public hearing on February 28, 2012 to receive testimony and public comments on these proposals. We will summarize those comments and our responses thereto in our next report to you. If you have any questions or need additional information, please contact me directly at 225.925.6481 or mbroussard@pharmacy.la.gov.

For the Board:

Malcolm J. Broussard
Executive Director

Pharmacy Program
Tel. 225.922.0852
Fax. 225.925.6499

CDS Program
Tel. 225.925.4770
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PMP Office
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Executive Office
Tel. 225.925.6496
Fax. 225.922.0316

OFFICE OF THE STATE REGISTER INSERTION ORDER (effective 1/1/11)
Claiborne Building 1201 North Third Street Suite 3-220 Post Office Box 94095
Baton Rouge, LA 70804-9095 (225)342-5015 FAX (225)342-0284

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JCSB

(SUBMIT A SEPARATE INSERTION ORDER PER DOCUMENT)

OFFICE OF THE STATE REGISTER

EMERGENCY RULE NOTICE OF INTENT RULE POTPOURRI

REFER TO INSTRUCTIONS ON REVERSE SIDE

This is your authority to publish in the (month) January, 20 12 Louisiana Register the document indicated above.

Board of Pharmacy

Office/Board/Commission promulgating this document

Malcolm J Broussard Executive Director

(name) (title)
Name and title of person whose signature will appear in the publication (at the end of the document)

Health and Hospitals

Department under which office/board/commission is classified

Malcolm J Broussard 225.925.6481 225.922.0316

(name) (phone) (fax)
Name, phone number, and FAX number of person to contact regarding this document

mbroussard@pharmacy.la.gov

E-mail address of contact person

Provide a short descriptive listing for this document to be used in the *Louisiana Register's* TABLE OF CONTENTS/INDEX (note: this description should match the fiscal statement title, if sending a Notice of Intent:

*If sending a diskette, indicate the name of the file on diskette:

Pharmacist-in-Charge (PIC) Requirements

Important: If submitting both an Emergency Rule (ER) and a Notice of Intent (NOI) to be published this month, AND if the rule text in the ER is identical to the rule text in the NOI, check here:

Malcolm J Broussard
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Print Name and Title of Agency Head or Designee

CERTIFICATION OF AVAILABLE FUNDS

DOCUMENT # _____

ISIS AGENCY: I certify the availability of fiscal year _____ appropriated funds for the payment of the above referenced publication and authorize the processing of an Interagency Billing with the following coding on the 30th of the month of the publication. Attach supplemental sheet for additional lines of coding.

AGENCY ORGANIZATION # OBJECT SUB-OBJECT REPORTING CATEGORY

NON-ISIS AGENCY: I certify the availability of fiscal year 11-12 appropriated funds for the payment of the above referenced publication and agree to place corresponding invoice in line for payment upon receipt.

Billing Address for Agencies:

Louisiana Board of Pharmacy

Agency Name

3388 Brentwood Drive

Street Address or Post Office Box

Baton Rouge LA 70809

City State Zip Code

Malcolm J Broussard 225,925,6481
Signature of Agency Head or Designee - Phone #

Lines/Other Charges _____ Typesetting \$ _____ TOTAL \$ _____

Notice of Intent

Department of Health and Hospitals Board of Pharmacy

LAC 46:LIII.1105 – Pharmacist-in-Charge

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend §1105 – *Pharmacist-in-Charge* of its rules. In particular, the proposed amendment will impose a new two-year practice requirement on the qualifications required of a pharmacist to accept an appointment as the pharmacist-in-charge of a Louisiana-licensed pharmacy, and in addition, will require the personal presence of the pharmacist-in-charge for a minimum period of time.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed amendment. A public hearing on this proposed rule change is scheduled for Tuesday, February 28, 2012 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter A. General Requirements

...

§1105. Pharmacist-in-Charge

A. The opportunity to accept an appointment as the Pharmacist-in-Charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.

1. The acquisition of the PIC privilege shall require:
 - a. possession of an active Louisiana pharmacist license;
 - b. active pharmacy practice for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and
 - c. the completion of the Affidavit of Responsibility and Duties described below.
2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week the PIC shall be present and practicing at least 50% of the normal business hours.

A.B. ...

B.C. ...

C. D. ...

D. E. ...

E. F. ...

F. G. ...

G. H. ...

H. I. ...

I. J. ...

J. K. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004, amended LR.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Dept.: Health and Hospitals
Statement: Malcolm J. Broussard Executive Director Office: Board of Pharmacy
Phone: (225) 925-6481 Title: Pharmacist-in-Charge
Return Address: Date Rule
3388 Brentwood Drive Takes Effect: June 1, 2012 (est.)
Baton Rouge, LA 70809-1700

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

It is estimated that implementation of the proposed rule will cost the agency \$500 in FY 11-12, for printing costs.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)

We can discern no measurable impact on revenue collections for state or local governmental units.

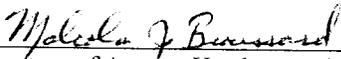
III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The Board proposes to amend §1105 of its rules to require any pharmacist have at least two years of practice experience prior to accepting an appointment as the pharmacist-in-charge of a Louisiana-licensed pharmacy, and further, to require the pharmacist-in-charge to be personally present in the pharmacy for which he serves as the pharmacist-in-charge for at least twenty hours per week.

The pharmacists affected by the proposed rule would be newly-licensed pharmacists with less than two years experience. They could accept a staff member appointment but not a pharmacist-in-charge appointment. To the extent any of the management level positions provide additional compensation, newly-licensed pharmacists would have a delayed eligibility for that additional compensation.

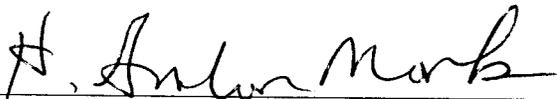
IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

We can discern no measurable effect on competition or employment.


Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

December 20, 2011
Date of Signature


Legislative Fiscal Officer or Designee

1-4-2012
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board proposes to amend §1105 of its rules to require any pharmacist have at least two years of practice experience prior to accepting an appointment as the pharmacist-in-charge of a Louisiana-licensed pharmacy, and further, to require the pharmacist-in-charge to be personally present in the pharmacy for which he serves as the pharmacist-in-charge for at least twenty hours per week.

A copy of the Notice of Intent is appended.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The Board has observed a trend of newly-licensed pharmacists accepting an appointment as the pharmacist-in-charge of a pharmacy without the experience required to manage a practice site. Moreover, an increasing number of young pharmacists have been disciplined for their failure to comprehend and perform the additional responsibilities attached to a pharmacist-in-charge appointment.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

We can discern no measurable impact on the Board's expenditures, other than the printing costs of promulgation.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?
(a) ____ Yes. If yes, attach documentation.
(b) ____ No. If no, provide justification as to why this rule change should be published at this time.

The Legislature has not appropriated the funds. The Board of Pharmacy operates purely on self-generated funds, and the Board has sufficient funds budgeted and available for the promulgation process.

- D. Compliance with Act 820 of the 2008 Regular Session

- (1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of 'small businesses,' we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. However, we can estimate the number using a specific classification of pharmacy permits; in particular, we do not believe the number of impacted small businesses would exceed 600.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

There are no reporting requirements or costs associated with the proposed rule.

- (3) A statement of the probable effect on impacted small businesses.

We can discern no measurable effect on small businesses from the proposed rule.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

We can discern no alternative methods of achieving the same purpose of the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 500	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 500	\$ 0	\$ 0
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

We anticipate the printing costs for the implementation of the proposed rule to approximate \$500 (\$250 for the notice of intent and the same amount for the final rule). We can discern no additional changes in the Board's costs.

3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 500	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 500	\$ 0	\$ 0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board currently has sufficient funds budgeted and available to complete the promulgation process.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

We can discern no impact on local governmental units.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 11-12</u>	<u>FY 12-13</u>	<u>FY 13-14</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
TOTAL	\$ 0	\$ 0	\$ 0

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

We can discern no change in the revenue collections of state or local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

Every one of the 1,700 pharmacies licensed by the Board is required to appoint a pharmacist as the pharmacist-in-charge of the pharmacy. That pharmacist is responsible for ensuring the pharmacy's compliance with all of the federal and state pharmacy laws and rules governing pharmacy practice. Currently, the only requirement to accept a pharmacist-in-charge appointment is an active and unrestricted license. There are no requirements as to whether (or for how much time) the pharmacist is required to be present in that pharmacy.

The persons directly affected by this proposed rule will be those pharmacists who have been licensed for less than two years (currently, approximately 650 of the total 7,100 licensed pharmacists). To the extent any of those newly-licensed pharmacists would desire or seek an appointment as the pharmacist-in-charge of a Louisiana-licensed pharmacy, they would be prohibited from doing so until they acquired the two years of practice experience.

Finally, the proposed rule will require the pharmacist-in-charge to be personally present in the pharmacy for at least twenty hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's ordinary course of business requires the pharmacy to be open for less than twenty hours per week, then the pharmacist-in-charge shall be personally present at least fifty percent of the time the pharmacy is open.

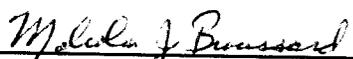
Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

We can discern no impact on receipts and/or income resulting from the proposed rule.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

We can discern no measurable impact on competition or employment in the public or private sectors.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

December 20, 2011
Date of Signature

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard**
Executive Director
Telephone: (225) 925-6481
Return Address: 3388 Brentwood Drive
Baton Rouge, LA 70809-1700

Dept.: **Health and Hospitals**
Office: **Board of Pharmacy**
Title: **Pharmacist-in-Charge**
Date Rule Takes Effect: **June 1, 2012 (est.)**

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

- I. The establishment of less stringent compliance or reporting requirements for small businesses.

The proposed amendment seeks to require at least two years of experience for any pharmacist desiring to accept an appointment as the pharmacist-in-charge of a Louisiana-licensed pharmacy, and further, the rule seeks to require a minimum amount of time the pharmacist-in-charge shall be personally present in the pharmacy, i.e., at least twenty hours per week. The proposed amendment specifically provides an exception for small businesses that are not open at least twenty hours per week, wherein the minimum amount of time is defined as fifty percent of the time the pharmacy is open.

- II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no schedules or deadlines for reporting requirements in the proposed amendment.

- III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no reporting requirements in the proposed amendment.

- IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

There are no design standards in the proposed amendment. There is an alternative operational standard for small businesses in the proposed amendment.

- V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

The proposed amendment seeks to remedy an apparent deficit in the competency of newly-licensed pharmacists to manage pharmacy practice sites by requiring at least two years of practice experience prior to accepting an appointment as the pharmacist-in-charge of a Louisiana-licensed pharmacy. Since the competent management of a pharmacy has a direct impact on the public's health and safety, the Board sought to strike a balance between a longer (five year) and shorter (one year) option. The Board believes an exemption from the competency standard is not in the public's best interest. With respect to the minimum amount of time required for the pharmacist-in-charge to be personally present in the pharmacy, the proposed amendment contains an alternative standard for those pharmacies open less than twenty hours per week.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee

December 20, 2011

Date of Signature

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard**
Executive Director
Telephone: (225) 925-6481
Return Address: 3388 Brentwood Drive
Baton Rouge, LA 70809-1700

Dept.: **Health and Hospitals**
Office: **Board of Pharmacy**
Title: **Pharmacist-in-Charge**
Date Rule Takes Effect: **June 1, 2012 (est.)**

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

We can discern no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

We can discern no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

We can discern no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

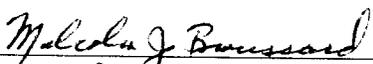
We can discern no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

We can discern no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

We can discern no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director

Typed Name and Title of Agency Head or Designee

December 20, 2011

Date of Signature